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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,832	12/28/2000	Henry Hirschberg	Q041	8673

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EXAMINER
SHAY, DAVID M

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 03/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

NM

Office Action Summary

Application No.	Applicant(s)
09/750832	Hirschberg
Examiner	**Group Art Unit**
D. Stay	3739

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE —3— MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on December 3, 2002.

☑ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1, 2, 4, 6-11, 15-17, 19, 21-37, & 40 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☑ Claim(s) 1, 2, 4, 6-11, 15-17, 19, 21-37, & 40 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachm nt(s)

☐ Information Disclosure Stat ment(s), PTO-1449, Paper No(s)._____

☐ Interview Summary, PTO-413

☐ Notice of Ref rence(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notic of Draftsperson's Patent Drawing Revi w, PTO-948

☐ Other_____

Office Action Summary

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4, 6-11, 15, 16, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dietrich et al in combination with Chen et al and Lee. Dietrich et al teaches a device as claimed except for the transparent plug; the self sealing membrane; and the laser which allows the patient to move about freely. Chen et al teach an indwelling PDT device including multiple lumens, a plug and a valve, and irradiation over long period of time. Lee teaches the desirability of employing self sealing membranes and shows a funnel-shaped opening. It would have been obvious to employ the self sealing membranes of Lee and the plugs claimed since these would enable the fluid to be retained in the balloon more easily and prevent the excursion of blood or other fluids and to provide low dosage PDT over a longer period of time, since this is more effective against the diseased tissue, as taught by Chen et al, or alternatively to form the spherical radiator of Chen et al as a balloon, since this enables more even illumination in the event the cavity is larger than the radiator, since the balloon can be inflated and would further allow less traumatic removal and insertion of the device, since the balloon can be deflated and in either case to provide a funnel shaped entrance, as shown by Lee since this would tend to guide the inserted device into the passage, which is notorious in the art, thus producing a device such as claimed.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dietrich et al in combination with Chen et al and Lee as applied to claims 1, 2, 4, 6-11, 15, 16, 19, and 21 above, and further in view of Hayman et al. Hayman et al teach the desirability of combining PDT and radiation treatment. It would have obvious to the artisan of ordinary skill to employ a

radioactive wire, since this a useful adjunct to PDT, as taught by Hayman et al thus producing a device such as claimed.

Claims 22-26, 28-31, 33-37, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dietrich et al in combination with Chen et al and Lee. The teachings of Dietrich et al, Lee and Chen et al are as set forth above, and additionally the total implantation of the irradiator and the use of PDT on breast cancer by Chen et al. Thus it would have been obvious to the artisan of ordinary skill to combine these old and well known teachings and provide the stated modifications for the reasons set forth above to produce a method such as claimed and to prolong the treatment over the course of months or a year, since some cancers are very difficult to irradiate, thus producing a method such as claimed.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dietrich et al in combination with Chen et al and Lee as applied to claims 22-26, 28-31, 33-37, and 40 above, and further in view of Hayman et al. The teachings of Hayman and the motivations for combination thereof are essentially those set forth above. Thus it would have been obvious to the artisan of ordinary skill to combine these old well known teachings to produce a method such as claimed.

Applicant makes several arguments regarding the combination. Applicant firstly argues that the intended use of the balloon recited in claim 1 is not fulfilled by the balloon of Dietrich et al. The examiner respectfully notes that the functional phrase "for disposition, into said body cavity and which when inflated..." is merely functional and is not of the proper form to be accorded structural weight (see MPEP 2181).

Regarding Chen et al, while applicant's assertion that "Chen cannot be used to practically and successfully treat the subject brain cancer." The examiner notes that as an issued

patent Chen et al enjoys a presumption of validity, and thus applicant's unsupported assertion is not convincing. This aside, Chen et al clearly discusses the application of PDT over the course of several weeks with a probe that is left in place (see column 7, line 55 to column 8, line 21); and discusses the patient being ambulatory (see column 10, lines 38-41). Lastly regarding Figures 16-18, Chen et al further discusses an optical fiber which is removable (see column 23 lines 43 to column 24, line 3) and also discusses the injection and removal of fluids (see column 24, lines 4-15). This latter teaching being sufficient motivation to include the teachings of Lee. While Lee does not disclose the motivation employed by applicant, this is not required for the propriety of the rejection. The device of Chen et al (see e.g. Figure 18) provides a means for repeated insertions and removal of an optical fiber. It is also respectfully noted that a *prima facie* case of obviousness is established by presenting evidence indicating that the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the teachings before him to make the proposed combination or other modification (see *In re Lintner*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972)). The disclosure of each of the references relied upon is considered for what it fairly teaches one of ordinary skill in the art, including not only the specific teachings (see *In re Boe*, 355 F.2d 961, 148 USPQ 507 (CCPA 1966)), but also the inferences which one of the ordinary skill in the art would reasonably have been expected to draw therefrom (see *In re Preda*, 401 F.2d 825, 159 USPQ 342 (CCPA 1968)). Finally, one of ordinary skill in that art is presumed to possess a reasonable level of skill in that art, and not a lack thereof (see *In re Sovish*, 769 F.2d 738, 226 USPQ 771 (Fed. Cir. 1985)).

Thus the clear disclosure of Chen et al that the devices are to be implanted for as long as several weeks; that the devices are to be used by ambulatory patients; and that optical

fibers can be removably inserted in a sealing relationship with the catheter, would clearly lead one having ordinary skill to employ a removable fiber in an indwelling device. Thus applicant's arguments are not convincing. Similar arguments regarding the method are also not convincing.

Applicant's arguments filed December 3, 2002 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set for the above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number 703-308-2215.

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330

Shay/dl

March 21, 2003